UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,917	02/22/2002	Patrick Cadet	09598-006001	7797

26191 7590 06/06/2005

FISH & RICHARDSON P.C.
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
LANDSMAN, ROBERT S	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,917	CADET ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-32* is/are pending in the application.

4a) Of the above claim(s) *3,5,11,13 and 15-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4, 6, 7, 9, 10, 12 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

A. The Amendment dated 4/20/05 has been entered into the specification.

B. Claims 1-32 were pending. Claim 8 has been canceled. Claims 3, 5, 11, 13 and 15-32 are withdrawn as being drawn to a non-elected invention. Therefore, claims 1, 2, 4, 6, 7, 9, 10, 12 and 14 are the subject of this Office Action.

C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. Claims 1, 2, 4, 6, 7, 9, 10, 12 and 14 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action mailed 12/16/04. Applicants argue that it is clear from the specification that mu3 is a splice variant of mu1 and mu2 receptors and that other mu3 receptors can be obtained using PCR based on mu1 and mu2 sequences. Applicants further argue that a receptor is considered a mu3 receptor if it has higher affinity for DAMGO than for morphine.

These arguments have been considered, but are not deemed persuasive. While it is disclosed in the specification that mu3 is a splice variant of mu1/mu2, there is no requirement for this in the claims. The claims are broader than the disclosure since the only limitation is that the receptor has higher affinity for DAMGO than for morphine. While this limitation was added to claim 1 as per the Examiner's suggestion, the claims are still of excessive breadth. Claim 1 encompasses any mu3 receptor from any species whereas Applicants have only disclosed a mu3 receptor of SEQ ID NO:4, a human receptor, having the variation seen in SEQ ID NO:1. The specification does not teach other splice variants of mu3 in humans, nor of mu3 receptors from other species, nor is there anything in the claims which require that the mu3 receptor is a splice variant of mu1 or mu2.

This is further problematic given, for example, claim 2, which provides coordinates identifying various lengths and percent identity for the region corresponding to SEQ ID NO:1. As written, claim 1 is excessive since there is no recitation of the receptor having mu1 or mu2 sequences. Therefore, any receptor which has an increased affinity for DAMGO relative to morphine would be covered by the claims, regardless of whether or not is a splice variant of mu1/mu2 or structurally distinct. Given this, the

only structural requirement in claim 2 are for the residues of SEQ ID NO:1 which is only a small portion of the entire receptor. Since the claim recites that the variant only has to be 65% identical to 15 bases of SEQ ID NO:1 (5 amino acids), which is 9-10 amino acids, this breadth is also excessive. In this embodiment, Applicants have only clearly defined 5 of 314 residues of the protein. There are no teachings in the specification which residues are required for protein function. Though it may be arguable that mu1 and mu2 receptors are well-known, Applicants have still not identified the residues critical for mu3 activity. Therefore, claiming that only 5 of 26 residues must be retained for function warrants undue experimentation, unless Applicants can provide evidence that it was well-known at the time of the invention which residues are required for mu3 receptor activity.

Regarding claims to hybridization, the same issues would apply. However, there is no structural requirement for these encoded proteins. All that is required is hybridization.

3. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 1, 2, 4, 6, 7, 9, 10, 12 and 14 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on page 4 of the Office Action mailed 12/16/04. Applicants argue that it is clear from the specification that mu3 is a splice variant of mu1 and mu2 wherein a specific sequence of mu1/mu2 has been replaced with other amino acids. Applicants further argue that common molecular cloning techniques can be used to identify other variants.

These arguments have been considered, but are not deemed persuasive for the reasons discussed above in the scope of enablement rejection. Applicants have only adequately described one species of mu3 receptor, that of SEQ ID NO:4. No other species are described, or structurally contemplated, within the instant specification. Therefore, one skilled in the art cannot reasonably visualize or predict critical nucleic acid residues which would structurally characterize the genus of nucleic acids encoding the genus of mu3 proteins claimed, because it is unknown and not described what structurally constitutes any different nucleic acids encoding mu3 receptors, or nucleic acids encoding mu3 receptors from any different species, which are further not described; thereby not meeting the written description requirement under 35 USC 112, first paragraph.

4. Claim Rejections - 35 USC § 112, first paragraph – new matter

Claims 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite "consisting essentially of." Support for this limitation cannot be found in the specification. Furthermore, if no verbatim support is found, the phrase will be interpreted as "comprising."

5. Claim Rejections - 35 USC § 112, second paragraph

A. All rejections under 35 USC 112, second paragraph, have been withdrawn in view of Applicants' amendments to the claims.

6. Claim Rejections - 35 USC § 102

A. The rejection of claims 6 and 7 under 35 USC 102 has been withdrawn in view of Applicants' arguments that Birren do not teach an "isolated" nucleic acid, nor one which preferentially binds DAMGO to morphine.

B. The rejection of claim 9 under 35 USC 102 has been withdrawn in view of Applicants' amendment to the claim. Fimiani do not teach a recombinant cell.

7. Conclusion

A. No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 10 AM – 7 PM (eastern); alt F 10 AM – 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman
Primary Examiner
Art Unit 1647

ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER